MAY 0 2 2014
K132004

510(k) Summary

807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Cork Medical Products
Company Address:	6406 Castleway Court Indianapolis, IN 46250
Telephone:	317-849-2675
Fax:	866-271-2580
Contact Person:	Jon D. Speer
Date Prepared:	April 29, 2014

DEVICE NAME **807.92(a)(2)**

Trade Name:	Cork Medical Products NPWT Wound Dressing Kit
Common / Usual Name:	Cork NPWT Wound Dressing Kit
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Device Class:	Class II
Panel:	General & Plastic Surgery

PREDICATE DEVICE **807.92(a)(3)**

Table 1 - Predicate Devices

Company	Brand Name	510(k) Number
Genadyne Biotechnologies, Inc.	A4 Wound Dressing Vacuum System Kit	K082676
Genadyne Biotechnologies, Inc.	A4-XLR8 Foam Dressing	K092992

DEVICE DESCRIPTION **807.92(a)(4)**

Cork Medical Products NPWT Wound Dressing Kit is comprised of components necessary to dress a wound for negative pressure wound therapy. The kit includes reticulated, 30 pores per inch (PPI), polyether, polyurethane foam; transparent polyurethane film drape with adhesive backing; and port pad assembly comprised of silicone port pad, drainage tubing, luer connector, pinch clamp, and transparent polyurethane film drape with adhesive backing.

The kits are available in two (2) sizes: medium and large based on the size of the foam. The medium foam is: 0.75" x 5" x 8". The large foam is 0.75" x 6" x 10". Each kit is single-use and housed in a Tyvek peel pouch, which is sterilized using ethylene oxide.

DEVICE INTENDED USE **807.92(a)(5)**

Cork Medical Products NPWT Wound Dressing Kit is intended to be used in conjunction with the Genadyne XLR8 Pump to deliver negative pressure wound therapy to the wound.

When used in conjunction with a NPWT pump system, Cork Medical Products NPWT Wound Dressing Kit is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

PREDICATE PRODUCT COMPARISON TABLE **807.92(a)(6)**

Table 2 - Predicate Comparisons

Component	Cork Medical Products NPWT Wound Dressing Kit K132004	Genadyne Biotechnologies, Inc. A4 Wound Dressing Vacuum System Kit & A4-XLR8 Foam Dressing K082676 & K092992 (predicate)
Wound Foam – Material	Reticulated polyether based polyurethane foam (A30M)	Reticulated polyether based polyurethane foam (A30M)
Wound Foam – Sizes	Medium: 0.75" x 5" x 8" Larger: 0.75" x 6" x 10"	Small: 2.5-cm x 6-cm x 6-cm (~1" x 2.36" x 2.36") Medium: 2-cm x 10-cm x 15-cm (~0.79" x 3.94" x 5.91") Large: 2.5-cm x 15-cm x 25-cm (~1 x 5.91" x 9.84")
Wound Foam – Biocompatibility	Yes – data provided by UFP Technologies (foam manufacturer)	Yes
Wound Foam – 510(k)	To be determined	K092992
Wound Drape – Material	Transparent polyurethane film with adhesive backing	Transparent film dressing
Wound Drape – Biocompability	Yes – data provided by George Medical for DermaMed medical grade acrylic	None specified
Wound Drape – 510(k)	K951842 & K990955 (via George Medical, LLC)	K082676
Port Pad Assembly	Silicone port pad Drainage tubing Luer connector Pinch clamp Port Pad Skirt (Transparent polyurethane film with adhesive backing)	Silicone port pad Drainage tubing Luer connector Pinch clamp Transparent film with adhesive backing
Port Pad – 510(k)	K132004 (this submission)	K082676
Sterilization Method	Ethylene Oxide	Individual kit components individually sterilized by Ethylene Oxide or Gamma Irradiation

Regulation Number / Product Code	21 CFR 878.4780 / OMP	21 CFR 878.4780 / OMP
Indications for Use	Cork Medical Products NPWT Wound Dressing Kit is intended to be used in conjunction with the Genadyne XLR8 Pump to deliver negative pressure wound therapy to the wound. When used in conjunction with a NPWT pump system, Cork Medical Products NPWT Wound Dressing Kit is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.	K082676: The Genadyne A4 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. (NOTE: K082676 includes accessory kit comprised of gauze, transparent film dressing, and silicone flat drain.) K092992: Genadyne A4-XLR8 Foam Dressing is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound. Genadyne A4 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissues debris.

NONCLINICAL TESTS **807.92(b)(1)**

To ensure the Cork Medical Products NPWT Wound Dressing Kit is substantially equivalent to the Genadyne A4 Wound Dressing Vacuum System Kit and A4-XLR8 Foam Dressing, Cork Medical analyzed the performance of the Cork Wound Kit against the predicate device. The specific head to head performance testing conducted to demonstrate substantial equivalence is:

- Continuous Mode Low Negative Pressure (-40-mmHg) Test
- Continuous Mode Typical Negative Pressure (-125-mmHg) Test
- Continuous Mode High Negative Pressure (-200-mmHg) Test
- Intermittent Mode Test
- Leakage Alarm Test
- Blockage Alarm Test
- Canister Full Alarm Test

Performance tests used simulated wound exudate. Pressure measurements were taken using a wound test bed fixture.

SUMMARY OF BIOCOMPATIBILITY COMPLIANCE TESTS **807.92(b)(1)**

A Biocompatibility Risk Assessment was completed by Nelson Laboratories evaluating the biocompatibility of the entire Cork Medical Products Wound Dressing Kit.

Additional biocompatibility testing was performed on the wound foam and wound drape components, the patient contacting components, for surface device, breached or compromised surface, with a prolonged (24 hours – 30 day) contact per ISO 10993 testing standards. The specific biocompatibility testing performed on the wound foam and wound drape was:

- Cytotoxicity Test
- Intracuteneous Reactivity Test
- Sensitization Test

All biocompatibility test results were negative and passed the pre-defined test acceptance criteria.

Additional biocompatibility information has been provided for each of the individual components included in the Cork Medical Products Wound Dressing Kit, as follows:

- Wound Foam
    - Summary of ISO 10993 biocompatibility tests performed on material by UFP Technologies listed on A-30M specification.
    - Crest Foam A-30M MAF 1837- FDA Registration Certificate.
- Wound Drape & Port Pad Drape
    - Summary of ISO 10993 biocompatibility tests performed on DermaMed medical grade acrylic adhesive provided.
    - NOTE: The port pad drape is not in contact with the patient. Biocompatibility not required.
- Silicone Port Pad
    - This material is not in contact with the patient. Biocompatibility not required.
    - Wacker Silicones Elastosil® R 420/60 S.
- Port Pad tubing
    - This material is not in contact with the patient. Biocompatibility not required.
    - Dow Corning Silastic® RX-50 medical grade tubing.
- Luer connector – This material is not in contact with the patient. Biocompatibility not required.
- Pinch Clamp – This material is not in contact with the patient. Biocompatibility not required.

CLINICAL TESTS **807.92(b)(2)**

No clinical testing provided.

SUBSTANTIAL EQUIVALENCE **807.92(b)(3)**

The results of the nonclinical tests performed demonstrate the performance of the Cork Medical Products Wound Dressing Kit is substantially equivalent to the performance of the predicate device, Genadyne A4 Wound Dressing Vacuum System Kit and A4-XLR8 Foam Dressing. The results of the nonclinical tests and summary of biocompatibility compliance tests demonstrate the Cork Medical Products Wound Dressing Kit is safe.

To further establish substantial equivalence to the predicate device, Genadyne A4 Wound Dressing Vacuum System Kit and A4-XLR8 Foam Dressing, Cork Medical Products evaluated the indications for use, materials, technology, and product specifications for the components of the product. As a result of this analysis along with performance testing, Cork Medical has demonstrated substantial equivalence of the Cork Medical Products NPWT Wound Dressing Kit for its indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

Cork Medical Products LLC
% Mr. Jon Speer
Creo Quality, LLC
P.O. Box 1784
Martinsville, Indianapolis 46151

Re: K132004
Trade/Device Name: Cork Medical Products NPWT Wound Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 7, 2014
Received: March 19, 2014

Dear Mr. Speer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132004

Device Name
Cork Medical Products NPWT Wound Dressing Kit

Indications for Use *(Describe)*
Cork Medical Products NPWT Wound Dressing Kit is intended to be used in conjunction with the Genadyne XLR8 Pump to deliver negative pressure wound therapy to the wound.

When used in conjunction with a NPWT pump system, Cork Medical Products NPWT Wound Dressing Kit is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

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